



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

DATE: September 15, 2022

TO: Nina F. Schor, M.D., Ph.D.
Deputy Director for Intramural Research, NIH

FROM: Senior Animal Welfare Program Specialist, Office of Laboratory Animal Welfare

SUBJECT: Animal Welfare Investigation (NCI #26-22) - Animal Welfare Assurance
A4149-01 [Case 17D]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 5, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the NIH Intramural Research Program. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the National Cancer Institute Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to failure to adhere to the IACUC-approved protocol. The final report states in December 2021, 27 mice underwent an approved surgical procedure, however, the surgical technique used by the laboratory staff differed from the approved description in the protocol. Also, the lab exceeded the number of mice expected to undergo surgery. The findings associated with this incident included: inappropriate surgical technique, inadequate analgesia, inappropriate aseptic technique, and lack of appropriate hemostasis. It is stated the animals were observed by the veterinary staff and no serious adverse effects following surgery were noted. A review of the surgery documentation and a discussion with the research staff revealed the noncompliance.

In response, the veterinary staff is retraining the research staff responsible for the incident. Also, the next round of surgeries will be conducted with a veterinarian present. The matter was discussed at the ACUC meeting on June 8, 2022 and corrective measures were approved.

Based on its assessment of this explanation, OLAW understands that the NIH Intramural Research Program has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,
Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn
T. Tubbs -S
Date: 2022.09.15 08:05:36
-04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Dr. Remy Bossulet

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Thursday, September 15, 2022 12:18 PM
To: Schor, Nina (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD); Denny, Stephen (NIH/OD) [E]; Wyatt, Richard G (NIH/OD) [E]; Bosselut, Remy (NIH/NCI) [E]
Subject: OLAW Case A4149-17D
Attachments: A4149-17D.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Good afternoon Dr. Schor,

Attached please find Dr. Tubbs' response to OLAW Case A4149-17D. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

July 5, 2022

TO: Brent C. Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Animal Welfare Investigations - Assurance D16-00602 (NCI 25-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Cancer Institute (NCI) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the failure of research personnel to utilize appropriate surgical techniques in accordance with the ACUC-approved animal study proposal.

The event was first reported to the NIH Office of Animal Care and Use by the NCI Acting Animal Program Director on May 9, 2022.

Please contact me or Dr. Stephen Denny, Director, Office of Animal Care and Use, if additional information or clarifications are required.

Michael M.
Gottesman -S

Digitally signed by Michael
M. Gottesman -S
Date: 2022.07.05 16:30:52
-04'00'

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. Bosselut
Dr. Denny



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Laboratory of Immune Cell Biology
Bldg. 37, Room 3016
Bethesda, Maryland 20892
Phone: 240 760-6866
Fax: 240 541-4483
E-Mail: bosselur@mail.nih.gov

Date: 6/29/2022

To: Dr. Michael M. Gottesman, M.D., Deputy Director for Intramural Research

From: Rémy Bosselut, M.D., Ph.D
ACUC Chair, NCI

Subject: Reportable Animal Incident: Improper surgical technique

In December, 2021, 27 mice assigned to a single approved ACUC protocol underwent a survival surgical limb amputation following intramuscular tumor injection. This procedure and experiment were described in the ACUC-approved protocol, but the surgical technique performed by the laboratory staff differed from the approved description. In addition, the laboratory exceeded the number of mice expected to undergo surgery by 5 mice. The main differences in the actual surgical technique were inappropriate surgical technique, inadequate analgesia, inappropriate aseptic technique, and lack of appropriate hemostasis. Veterinary staff in the facility observed the mice and did not note any serious adverse effects following the surgeries, but the protocol was not followed correctly. NCI veterinary staff became aware of this on May 9, 2022, following a review of the surgery documentation and a discussion with the laboratory staff.

Given the likely adverse effects on the animals as well as performance of activity out of line with the ACUC approved criteria, we reported this incident to the Office of Animal Care and Use (OACU).

This was the first such instance for this group. They expressed apologies for the mistake and the veterinary staff is retraining the laboratory staff responsible to ensure that this mistake does not happen again. The next round of additional surgeries will be conducted with a veterinarian present and following some steps by the lab to ensure the presence of appropriate analgesics. This issue was discussed at the NCI ACUC meeting on June 8, 2022. The committee approved the corrective measure.

Please feel free to contact me if you have any questions.

Sincerely,

(b) (6)

Rémy Bosselut, M.D., Ph.D
Chair, NCI ACUC

Cc: Tom Misteli, Ph.D.

Glenn Merlino, Ph.D.
Joshua Kramer, D.V.M., M.S.

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, August 10, 2022 12:48 PM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NCI 25-22))

Good afternoon Dr. Denny,

Thank you for sending us this report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Wednesday, August 10, 2022 11:05 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NCI 25-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Cancer Institute (NCI) ACUC address an animal incident involving mice. The event was first reported to the NIH Office of Animal Care and Use by the NCI Acting Attending Veterinarian on May 9, 2020.

If you have any questions please contact me via email or at the phone number listed below. Thank you, Steve

STEPHEN DENNY, DVM, MS, DACLAM, DACVPM | Director, Office of Animal Care and Use | NIH Bethesda Campus, Building 31/Room B1C37 |
Phone: (301) 435-2188 | **NIH . . . Turning Discovery Into Health** |